PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	§	
	§	
Donald L. MORTON *et al.*	§	
	§	Group Art Unit: 1813
Serial No.: 07/431,533	§	
	§	Examiner: H. Sidberry
Filed: November 3, 1989	§	
	§	Atty. Dkt.: CADL:002/PAR
For: URINARY TUMOR ASSOCIATED ANTIGEN, ANTIGENIC SUBUNITS AND METHODS OF DETECTION	§	

CERTIFICATION OF MAILING UNDER 37 C.F.R. §1.8

DATE OF DEPOSIT December 18, 1996

I hereby certify that this paper or fee is being deposited with the United States Postal Service under 37 C.F.R. 1.8 on the date indicated above and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.

Steven L. Highlander

DECLARATION OF RALPH A. REISFELD UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, Ralph A. Reisfeld, declare that:

1. I am Head of the Division of Tumor Cell Biology at the Scripps Research Institute, La Jolla, CA. I have held this position for 26 years. A copy of my *curriculum vitae* is already of record.

2. I have reviewed the abstract of Euhus *et al.*, 24th Annual Meeting of the American Society of Clinical Oncology Proceedings, May 22-24, 1988, and the claims pending in the above-captioned application. It is my understanding that the examiner in charge of the above-captioned application has alleged that the Euhus abstract is relevant to the patentability of the subject matter of the instant application.

3. The Euhus abstract merely relates to an antigen designated U-TAA. Yet, the abstract does not provide any information that would permit those of skill in the art to confirm that a given antigen, if isolated, was or was not the U-TAA of the abstract. Specifically, the Euhus abstract only identifies U-TAA as existing in IgG and IgM fractions in the serum of some melanoma patients, provides its predicted molecular mass and asserts that the antigen contains at least four subunits of varying molecular mass. It does not, however, provide any information on the amino acid sequence of this molecule. Thus, a meaningful description of this molecule is not provided by the abstract. Without such information, those of skill in the art would not know if they had isolated what Euhus *et al.* had designated as U-TAA.

4. Similarly, the Euhus *et al.* abstract is devoid of any information regarding the immunologic identity of the antigen. Though a murine antibody that binds U-TAA is mentioned, this antibody is neither described nor was it publicly available at the time the instant application was filed. Moreover, the method by which the murine antibody was produced (*e.g.* antigen composition, immunization regimen, selection criteria) is not described. Without such

information, those of skill in the art would not have had the Euhus antibody, much less been able to use it to determine if they had isolated what Euhus *et al.* had designated as U-TAA.

5. Therefore, based on my 40 years of experience in the isolation, purification and characterization of biological products similar to U-TAA, reproduction of the work described in the Euhus *et al.* abstract would have relied, almost entirely, on an empirical "trial and error" approach, and thus would have lacked any reasonable and reliable expectation of success from it inception. Even if those of skill in the art would have fortuitously reproduced the work described in the Euhus *et al.* abstract, they could not have confirmed such a success with the information available.

6. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful, false statements may jeopardize the validity of this application or any patent issued thereon.

11/26/96
Date

Ralph A. Reisfeld, Ph.D.